Reducing Delays in Hatch-Waxman Multidistrict Litigation

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Multidistrict litigation (MDL) under 28 USC § 1407 consolidates in one federal court the pretrial proceedings of related cases. This procedural mechanism has generally made complex litigation more efficient, but the Supreme Court has reduced its efficiency in some circumstances by prohibiting these courts from retaining all related cases for trial.[1]

Drug patent litigation is an area of particular concern. The Hatch-Waxman Act of 1984[2] (Hatch-Waxman or Act) provides a unique legal regime for the adjudication of disputes involving patented drugs and potential generic alternatives. Inefficiencies in Hatch-Waxman MDLs frustrate the Act's purpose by postponing generic competition that would drive down pharmaceutical prices.[3] Once consolidated cases are ready for trial, the MDL statute requires that they be remanded to their original courts. However, common factual issues and the need for consistent determinations of patent validity strongly favor one court's trying the cases together. These considerations spurred the original courts in one Hatch-Waxman MDL to re-transfer all of the cases to one court for trial under the conventional transfer statute—28 USC § 1404(a).[4]

Until recently, efficiency-minded pretrial courts could have avoided the delays caused by remand and re-transfer by transferring such cases to themselves for trial under § 1404(a). However, this ma-

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1 See *Lexecon v Milberg Weiss Bershad Hynes & Lerach*, 523 US 26, 28 (1998) (holding that a district court conducting pretrial proceedings has no authority to assign a transferred case to itself for trial).

2 The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub L No 98-417, 98 Stat 1585, codified in relevant part at 21 USC § 355 (2000).

3 See Drug Price Competition and Patent Term Restoration Act, HR Rep No 98-857, 98th Cong, 2d Sess 14 (1984), reprinted in 1984 USCCAN 2647, 2649 ("The purpose of Title I of the bill is to make available more low cost generic drugs."). For example, in the omeprazole MDL, the delay between pretrial proceedings and trial prolonged monopoly prices of the drug, thus earning AstraZeneca $12 million in monopoly rents per day of litigation and costing consumers hundreds of millions of dollars. See Ronald D. White, *Key Drug Patent Ruling Nears: Courts: Effort to Block Generic Versions of Prilosec Could Set Trend in the Industry*, LA Times C1 (May 28, 2002) (quoting a Morningstar analyst for this figure).

4 See Part II.B (discussing the omeprazole MDL).

neuver, known as self-transfer, arguably had no support in the language of § 1407, and the Supreme Court invalidated the practice in *Lexecon v Milberg Weiss Bershad Hynes & Lerach*.[5] While adhering to the text of § 1407, the Court's decision frustrated the purpose of Hatch-Waxman: namely, to promote competition in prescription drugs. To serve that purpose today, courts should utilize other procedural mechanisms to transfer and consolidate related Hatch-Waxman claims.

This Comment proceeds in three Parts. Part I explains MDL practice. Part II provides a background of the Hatch-Waxman Act and describes the problems *Lexecon* poses in Hatch-Waxman MDLs. Part III evaluates several approaches to this problem and proposes that courts use early § 1404(a) transfers to consolidate related Hatch-Waxman claims in one court for pretrial and trial proceedings.

I. MULTIDISTRICT LITIGATION

Until Congress enacted a statute governing multidistrict litigation, the procedures available to the federal judiciary had proven increasingly inadequate to handle complex litigation. Mass torts and antitrust violations, in particular, could yield thousands of claims filed in many district courts,[6] and conducting discovery of overlapping factual issues duplicated the efforts of both judges and litigants. Furthermore, litigating in multiple forums required parties and courts to coordinate their proceedings, a daunting task for a large volume of cases.

Existing procedures, including transfers under § 1404(a), offered little relief.[7] A § 1404(a) transfer allows one court to send a case to a so-called transferee court simply to promote the "convenience of parties and witnesses" and to serve the "interest of justice."[8] The proposed transferee court must be one in which the action "might have been

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5 523 US 26, 28 (1998).

6 The experience of nearly two thousand antitrust claims in thirty-five federal districts against electrical equipment manufacturers in the early 1960s demonstrated the inadequacy of existing procedures to the federal judiciary and Congress. See Phil C. Neal and Perry Goldberg, *The Electrical Equipment Antitrust Cases: Novel Judicial Administration*, 50 ABA J 621, 621 (1964) (explaining that a program of uniform, national pretrial procedures addressed these inadequacies).

7 Alternatively, a court lacking proper venue could transfer a case under 28 USC § 1406(a) (2000). A court with two related cases pending in the same district could consolidate them under FRCP 42(a). See Courts—Multidistrict Litigation—Transfer, HR Rep No 90-1130, 90th Cong, 2d Sess 3 (1968), reprinted in 1968 USCCAN 1898, 1900 (stating that, under FRCP 42(a), "consolidation for pretrial purposes is authorized only when multiple actions are pending in a single district court").

8 See 28 USC § 1404(a). See also *Norwood v Kirkpatrick*, 349 US 29, 32 (1955) (recognizing that Congress "intended to permit courts to grant transfers upon a lesser showing of inconvenience" than under the common law principle of forum non conveniens).

brought" originally.[9] In other words, the transferee court must have satisfied both jurisdiction and venue requirements when the complaint was filed.[10] Unfortunately, cases may share complex factual issues yet fail these requirements, so courts could not transfer and consolidate them. Congress filled this procedural vacuum by creating a mechanism known as multidistrict litigation.

A. The MDL Statute

The Multidistrict Litigation Act of 1968[11] (MDL Act or § 1407) created an alternate route to promote judicial efficiency in complex litigation by assigning transfer decisions to a body with a broader perspective than that of a district court focused only on the parties and witnesses in one case. Instead of relying on district courts, the MDL Act created the Judicial Panel on Multidistrict Litigation (Panel) to implement this new transfer mechanism.[12] In cases factually related to litigation pending elsewhere, a party seeking transfer under § 1407 must file a motion with the Panel—not the court.[13]

Lacking any personal jurisdiction or venue restrictions, § 1407 emphasizes aggregate efficiency more than § 1404(a) does. Section 1407 authorizes transfers to promote "the convenience of parties and witnesses and . . . just and efficient" litigation.[14] A transferred case must share one or more questions of fact with the case pending in the transferee court.[15] In addition, § 1407 grants authority to the transferee

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9 See 28 USC § 1404(a). See also *Van Dusen v Barrack*, 376 US 612, 616–24 (1964) (interpreting the phrase "where it might have been brought" as referring to the jurisdictional limitations imposed by federal, not state, statutes).

10 See *Hoffman v Blaski*, 363 US 335, 339, 342 (1960) (requiring a transferee court to have had proper "venue over the action and [the] ability to command jurisdiction over the defendants" when the complaint was filed). Subsequent courts have held that the transferee court must have been able to exercise subject matter jurisdiction as well. See, for example, *Packer v Kaiser Foundation Health Plan*, 728 F Supp 8, 12 (D DC 1989) ("Courts are in agreement that a district where plaintiff's action 'might have been brought' is one that has subject matter jurisdiction."). These requirements ensure that the defendant would have been subject to service of process in the transferee court. See *Foster-Milburn v Knight*, 181 F2d 949, 951–52 (2d Cir 1950) (Hand) (stating that a finding that suit could have been brought in a jurisdiction for purposes of § 1404(a) requires that the forum be one in which the complaint might have been filed and process served). Any judgment against a defendant denied service of process is null. See id at 952, citing *Pennoyer v Neff*, 95 US 714 (1877).

11 Multidistrict Litigation Act of 1968, Pub L No 90-296, 82 Stat 109 (1968), codified at 28 USC § 1407 (2000).

12 28 USC § 1407(a). See also Mark Herrmann, *To MDL or Not to MDL? A Defense Perspective*, 24 Litigation 43, 43 (Summer 1998) (discussing the mechanics of multidistrict litigation).

13 See 28 USC § 1407(a) ("Such transfers shall be made by the judicial panel on multidistrict litigation.").

14 Id.

15 Id ("When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings.").

court to conduct pretrial proceedings, after which cases shall be remanded to their original courts.[16] To obtain the remand, a party petitions the transferee court to suggest to the Panel that the case be remanded.[17]

B. The Panel in Practice

Transfers under § 1407 have dramatically changed complex litigation. From 1968 to 2003, the Panel transferred over 165,000 cases.[18] The factors influencing transfer decisions, however, arguably diverged from those authorized by the statute's text. For example, despite the convenience language in § 1407, the Panel has transferred cases over objections by both parties that doing so would be inconvenient.[19]

Perhaps motivated by the importance of aggregate efficiency to the Panel's transfer decisions, transferee courts adopted similar priorities by employing the controversial self-transfer order. The leading case supporting self-transfer was *Pfizer, Inc v Lord*.[20] Judge Miles Lord, after overseeing pretrial discovery in an antitrust MDL, ordered a § 1404(a) transfer of all remaining actions to his district for trial, presumably to promote convenience.[21] The Second Circuit affirmed the self-transfer, reasoning that § 1407 obligated only the Panel, not

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16 Id ("Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated.").

17 A party may also file a motion directly with the Panel. 28 USC § 1407(c)(ii). However, the Panel is generally reluctant to order remand absent a suggestion to that effect from the transferee court. See Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 FRD 425, 437 (providing Rule 7.6(d)). See also James W. Moore, 17 *Moore's Federal Practice* § 112.03[6][b] at 30 n 83 (3d ed 2003) (collecting cases that demonstrate this reluctance).

18 See Judicial Panel on Multidistrict Litigation, *Statistical Analysis of Multidistrict Litigation 2003* 4, online at http://www.jpml.uscourts.gov/StatisticalAnalysis2003.pdf (visited Mar 7, 2004). In addition, over 23,000 cases originally filed in transferee courts were subject to MDL proceedings. See id.

19 See, for example, *In re Fine Paper Antitrust Litigation*, 685 F2d 810, 819–20 (3d Cir 1982) (holding that judicial efficiency outweighed concerns about the convenience of the parties). See also Blake M. Rhodes, Comment, *The Judicial Panel on Multidistrict Litigation: Time for Rethinking*, 140 U Pa L Rev 711, 719–20 (1991) (noting that judicial economy is the "most influential factor in the transfer decision," while "the weight accorded the convenience factor has been minuscule").

20 447 F2d 122, 125 (2d Cir 1971) (allowing the self-transfer of remaining cases to the transferee court for trial).

21 See *In re Antibiotic Antitrust Actions*, 333 F Supp 299, 303–06 (SD NY 1971). Judge Lord had been specially assigned to the Southern District of New York to handle pretrial proceedings in the MDL. When Judge Lord transferred cases to his home district of Minnesota under § 1404(a), the plaintiffs petitioned the Second Circuit for a writ of mandamus vacating this order. See *Pfizer*, 447 F2d at 125 (denying the petition). After the transfers occurred, the plaintiffs petitioned the Eighth Circuit for a writ of mandamus. See *Pfizer, Inc v Lord*, 456 F2d 532, 544 (8th Cir 1972) (denying the petition). This experience exemplified Judge Lord's interventionist management style. See David Ranii, *A Judge's Public Battles*, Natl L J 1, 32, 34–35 (July 23, 1984) (describing Judge Lord's approach).

the transferee court, to remand cases.[22] Moreover, the Second Circuit found that self-transfer comported with the statute's purpose: to "promote the just and efficient conduct" of litigation.[23]

For the next twenty-five years, other transferee courts relied on *Pfizer* to order their own self-transfers.[24] Some commentators argued that transferee courts' familiarity with relevant factual complexities, acquired during discovery, uniquely qualified them to try the cases.[25] Consolidating related cases for trial sometimes prevented inconsistent judgments among the transferor courts,[26] and litigants may have had more incentive to settle when judges had control of cases from the pretrial stage until their termination.[27] Eventually, the Panel amended its rules to legitimize self-transfer.[28]

Despite these occasional benefits, self-transfer also engendered significant criticism.[29] Multidistrict litigation essentially sacrifices one important interest—the plaintiff's choice of forum—to promote another—judicial efficiency.[30] Although both the text and legislative history of § 1407 limited this tradeoff to pretrial proceedings, some trans-

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22 See *Pfizer*, 447 F2d at 124 ("Section 1407, however, deals *only* with the powers of the Multidistrict Litigation Panel, and not with the powers of the judge to whom the cases have been assigned by the Panel.").

23 See id at 125 (stating that, without self-transfer, the "inevitable result would be further extensive delay in litigation which already is among the most time consuming to appear on the federal dockets").

24 See *Lexecon v Milberg Weiss Bershad Hynes & Lerach*, 102 F3d 1524, 1541–42 (9th Cir 1996) (Kozinski dissenting) (collecting cases that "seem to sanction the practice," but noting that "not a single case after *Pfizer* has taken an independent look at the issue or dealt with the difficult questions it raises").

25 See Rhodes, Comment, 140 U Pa L Rev at 731 (cited in note 19) ("After spending weeks, or even months, governing pretrial stages of a matter, a judge acquires an unparalleled familiarity with the litigation.").

26 See id at 733 ("Conflicting decisions by transferor courts after remand are avoided as are multiple appeals from these decisions."). This is a particularly important benefit of self-transfer in cases involving purely federal questions, such as patent validity, or federal antitrust or securities claims.

27 For example, in asbestos MDLs, the settlement incentive existed for most of the duration of pretrial proceedings. As those proceedings concluded, a defendant's settlement incentive disappeared because § 1407 remands could add years of delay. See Valle Simms Dutcher, Comment, *The Asbestos Dragon: The Ramifications of Creative Judicial Management of Asbestos Cases*, 10 Pace Envir L Rev 955, 973–74 (1993).

28 See *Lexecon*, 523 US at 32–33 (citing then-Panel Rule 14(b) allowing self-transfer). The Panel has since deleted this language from its rules. See Rules of Procedure, 199 FRD at 426.

29 For a collection of this criticism, see *Lexecon*, 102 F3d at 1543 (Kozinski dissenting) ("Research discloses not a single commentator who has examined the question and found statutory support for the position taken by the federal courts. Seldom have courts and commentators diverged so widely in their treatment of a legal issue.").

30 See Carter G. Phillips, Gene C. Schaerr, and Anil K. Abraham, *Rescuing Multidistrict Litigation from the Altar of Expediency*, 1997 BYU L Rev 821, 823 ("In enacting [§ 1407], Congress has determined, correctly in our view, that such a compromise does not impose too great a cost in return for the benefits generated by the compromise—i.e., that the more efficient use of pretrial judicial resources outweighs the harm to litigants.").

feree courts exercised their discretion under § 1404(a) to order self-transfer and transgress this limit.[31] Moreover, transferee courts sometimes speciously applied choice-of-law principles to reach the convenient conclusion that one substantive law applied to all cases in an MDL, thus denying certain litigants their choice of law.[32] Finally, only the high standard of "abuse of discretion" could persuade a circuit court of appeals to overturn a transferee court's self-transfer decision.[33]

C. The Prohibition on Self-Transfer

Despite widespread criticism of self-transfer, the Supreme Court relied primarily on textual analysis to invalidate the practice in *Lexecon*. The case arose out of a class action and MDL pertaining to the Lincoln Savings & Loan scandal of the 1980s.[34] The class plaintiffs sued, among others, the consulting firm Lexecon, alleging that it had provided misleading reports of Lincoln's finances to banking regulators.[35] After the Arizona transferee court dismissed those claims in June 1992, Lexecon sued Milberg, the plaintiffs' law firm, in Illinois on several counts, including defamation under Illinois law.[36] The Panel transferred Lexecon's case to Arizona in June 1993, where the remaining cases in the MDL were pending.[37] Judge John M. Roll in the transferee court ordered the permanent transfer of the case to his court under § 1404(a) and held a jury trial of only the Illinois defamation

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31 See id at 825 (arguing that § 1407's mandate that transferred cases "*shall* be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred" leaves no discretion for transferee judges to self-transfer).

32 See Larry Kramer, *Choice of Law in Complex Litigation*, 71 NYU L Rev 547, 554–60 (1996) (characterizing one circuit court opinion as a "virtual 'how-to' manual of ways to manipulate choice-of-law analysis" in multidistrict litigation). Such manipulation is particularly troubling, given the growing propensity to consolidate mass tort claims in multidistrict litigation. See, for example, Dutcher, Comment, 10 Pace Envir L Rev at 976 (cited in note 27):

> When the Judicial Panel on Multidistrict Litigation broke its fourteen year precedent of refusing to consolidate asbestos cases under § 1407, the decision was hailed as a major step toward a final resolution of the asbestos crisis in the courts. The Panel transferred 26,000 asbestos cases from 87 federal districts to Judge Weiner in Philadelphia for pre-trial proceedings in July 1991.

33 See Rhodes, Comment, 140 U Pa L Rev at 745–46 & n 190 (cited in note 19) (collecting cases). But see *Lexecon*, 102 F3d at 1547 n 11 (Kozinski dissenting) ("I've found no case where an MDL court has been reversed for transferring a case to itself for trial.").

34 *Lexecon*, 523 US at 29 (discussing the background of the litigation).

35 Id.

36 *Lexecon*, 102 F3d at 1529. Lexecon argued that Milberg's suit had jeopardized its reputation for objective expert testimony and harmed its business. The firm said that its securities business declined by 65 percent, while its other business doubled, during the eight years of litigation. See Mayer, Brown, Rowe & Maw, LLP, Supreme Court Docket Report (Apr 26, 1999), online at http://www.appellate.net/docketreports/sc042699.asp (visited Mar 7, 2004).

37 See *Lexecon*, 523 US at 29–30 (discussing the transfer).

claim.[38] The jury found in favor of Milberg, and the Ninth Circuit affirmed.[39]

The self-transfer order in *Lexecon* illustrated the potential for misuse of § 1404(a). First, Judge Roll lacked any unique understanding of, or familiarity with, the underlying Lincoln litigation, because the judge who had handled those cases had recused himself.[40] In addition, the other cases in the MDL had settled before the trial of Lexecon's defamation claim,[41] so it was impossible to realize any efficiency gains by trying related cases in one forum.[42] Finally, Judge Roll had dismissed the other claims between Lexecon and Milberg, so the self-transfer order ultimately resulted in a trial of one Illinois-based claim before an Arizona jury.[43]

Disregarding the efficiency arguments supporting self-transfer generally, a unanimous Supreme Court held that the text of § 1407 demanded that the practice be prohibited.[44] The Court found unconvincing Milberg's literal interpretation of § 1407(a) as obligating only the Panel to remand cases after pretrial proceedings.[45] To the Court, the directive that cases "shall be remanded" to their original courts obligated both the Panel and transferee courts.[46] The Court similarly rejected Milberg's "subtle reading" of § 1407(a) that the remand obligation applied only to actions not "previously terminated" and that self-transfer effectively terminated the action for purposes of § 1407.[47]

Transferee courts responded to *Lexecon* immediately. Although there is no known figure for the frequency of self-transfer before

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38 See *Lexecon*, 102 F3d at 1531 (discussing the transfer and trial).

39 Id at 1540.

40 See id at 1529–30 (discussing the recusal).

41 See id at 1531 (stating that dismissal of the MDL preceded the transfer); *Lexecon*, 523 US at 32 ("Trial on the surviving defamation claim then went forward in the District of Arizona.").

42 See *Lexecon*, 102 F3d at 1547 n 13 (Kozinski dissenting) ("This was not even a situation where the parties and witnesses were already going to trial on related claims so it would have been convenient to try this case at the same time.").

43 See id at 1547 (Kozinski dissenting) ("Any advantage Judge Roll might have enjoyed in dealing with the facts was offset by the advantage a Chicago district judge would have had in instructing the jury as to Illinois law."). Judge Kozinski suggested that the Arizona jury may not have been impartial. See id at 1548 ("Lexecon was forced to trial in a forum where there was much popular feeling against Lincoln Savings, Charles Keating and those (like plaintiffs) who were associated with them.").

44 *Lexecon*, 523 US at 33–39. The Court also reached the same conclusion by reviewing the legislative history of § 1407, id at 39–40; Justice Scalia did not join this part of the opinion, id at 27.

45 See id at 32–34.

46 See id at 35 (holding that the text's "mandatory 'shall' . . . creates an obligation impervious to judicial discretion").

47 Id at 37 ("The trouble with this creative argument . . . is that the statute manifests no such subtlety.").

Lexecon,[48] the number of cases remanded by the Panel after *Lexecon* is suggestive. In the first twenty-nine years of multidistrict litigation, the Panel remanded only 3,781 actions to their transferor districts.[49] In 1998 (the year *Lexecon* was decided) alone, the Panel remanded 1,171 actions.[50] The following year, the Panel remanded another 4,363 actions.[51] Although *Lexecon* eliminated the inappropriate exercise of self-transfer that had long angered critics, the decision also prohibited the realization of the legitimate efficiency gains that had long motivated its practice.[52] The next Part explores one kind of multidistrict litigation in which self-transfer would likely have been welcome.

II. THE HATCH-WAXMAN ACT AND MULTIDISTRICT LITIGATION

Until 1984, the Food and Drug Administration's (FDA) drug approval process arguably stifled both the creation of brand name—or "pioneer"—drugs and the market potential of generic drugs.[53] Before approving a new drug, the FDA required safety and effectiveness studies that could last up to thirteen years.[54] To drug companies, this waiting period substantially undermined the commercial value of a patent.[55] Generic drug companies faced a less onerous approval process, but only for their versions of pioneer drugs approved before

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48 Justice Souter calculated the number of self-transfers to be 279. Id at 33 ("Thus, out of the 39,228 cases transferred under § 1407 and terminated as of September 30, 1995, 279 of the 3,787 ultimately requiring trial were retained by the courts to which the Panel had transferred them."). However, this figure actually represents the number of cases originally filed in courts that subsequently served as transferee courts for purposes of § 1407. See Leonidas Ralph Mecham, *Judicial Business of the United States Courts: 1997 Annual Report of the Director* 70 table S-22, online at http://www.uscourts.gov/judicial_business/s22sep97.pdf (visited Mar 7, 2004) (labeling this figure "Actions Reassigned to Transferor Judges within Transferee Court"). These cases remained after pretrial proceedings because there was no court—other than the court in which they existed—to which they could have been remanded.

49 See Leonidas Ralph Mecham, *Judicial Business of the United States Courts: 1999 Annual Report of the Director* 78 table S-21, online at http://www.uscourts.gov/judbus1999/s21sep99.pdf (visited Mar 7, 2004).

50 See id.

51 See Leonidas Ralph Mecham, *Judicial Business of the United States Courts: 2000 Annual Report of the Director* 72 table S-20, online at http://www.uscourts.gov/judbus2000/tables.s20sep00.pdf (visited Mar 7, 2004).

52 See Noreen Dever Arralde, Comment, *A Catalyst for Reforming Self-Transfer in Multidistrict Litigation:* Lexecon, Inc. v. Milberg Weiss, 72 St John's L Rev 623, 650 (1998) ("Federal district courts innovated self-transfer on the same policy grounds that motivated Congress: efficient administration of justice will be threatened without the power to consolidate actions.").

53 Before 1984, the 1962 Kefauver-Harris Amendments to the Pure Food and Drugs Act governed FDA drug approval procedures. See generally Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 J Legis 21, 23–24 (2002) (explaining pre-Hatch-Waxman regulations).

54 See id.

55 See id at 24 ("Brand name drug manufacturers argued this delay reduced the effective life of their patents and drastically diminished their recuperation of production costs.").

1962.[56] Given the time and expense of the normal approval process, few companies developed generic versions of post-1962 pioneer drugs.[57] As pre-1962 pioneer drugs became outdated, the regulatory advantages of generics diminished.[58]

A. The Hatch-Waxman Act

Congress passed the Hatch-Waxman Act primarily to foster development of generic drugs and thereby drive down the cost of prescription drugs.[59] Specifically, the Act created a streamlined approval process known as an Abbreviated New Drug Application (ANDA) for generic drugs. In an ANDA, a generic drug company makes one of four certifications to the FDA. Three can be handled directly by the FDA, which can easily confirm (1) that no patent information exists, (2) that any relevant patent has expired, or (3) the date on which the patent will soon expire.[60] The fourth requires a court's involvement because it asserts that a relevant patent exists but either is invalid or will not be infringed by the generic drug.[61] The conflict between the pioneer and the generic over this claim is a legal one that only a federal court has the authority to resolve.[62]

The Act provides some basic procedures to govern this litigation. For example, the mere filing of an ANDA containing a Paragraph IV certification may constitute an act of patent infringement.[63] A generic

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56 See HR Rep No 98-857, Part I at 3 (cited in note 3) ("FDA established a policy permitting the approval of a generic drug equivalent to a safe and effective pre-1962 pioneer drug.").

57 See Sarah M. Yoho, *Reformation of the Hatch-Waxman Act, An Unnecessary Resolution*, 27 Nova L Rev 527, 531 (2003) ("Due to the lack of finances to undertake the expensive process of clinical studies to prove a drug was safe and effective, few generic drugs entered the market.").

58 For pre-1962 pioneer drugs, generic drug companies could also file "paper NDAs" that relied on scientific literature to demonstrate drug safety and effectiveness. See Powell-Bullock, 29 J Legis at 24 (cited in note 53). Although expanding the paper NDA option to all drugs was possible, the FDA estimated that satisfactory literature existed for only 15 percent of post-1962 pioneer drugs. See HR Rep No 98-857, Part I at 3 (cited in note 3) ("This procedure is inadequate, however, because FDA estimates that satisfactory reports are not available for 85 percent of all post-1962 drugs.").

59 See HR Rep No 98-857, Part I at 3 (cited in note 3). Another purpose of the Act was to enhance the commercial value of drug patents. See id at 2 ("The incentive [for increased research and development] is the restoration of some of the time lost on patent life while the product is awaiting pre-market approval."). To this end, the FDA would extend market exclusivity according to the time required for human clinical trials and drug application review. See Powell-Bullock, 29 J Legis at 28 (cited in note 53).

60 21 USC § 355(j)(2)(A)(vii)(I)–(III).

61 21 USC § 355(j)(2)(A)(vii)(IV) (requiring "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted").

62 See *Ben Venue Labs, Inc v Novartis Pharmaceutical Corp*, 10 F Supp 2d 446, 456 (D NJ 1998) ("The FDA has stated that it lacks the resources and the expertise to review patents submitted with NDAs, and that it intends listing disputes to be settled privately.").

drug manufacturer making this certification must notify the pioneer drug company holding the patent, so the latter can bring a patent infringement action within the required period of forty-five days.[64]

Although the Act does not require that an infringement lawsuit be filed, in practice one will almost always result. Even if the pioneer drug company has a weak case,[65] litigation prolongs its monopoly.[66] The filing of a complaint triggers an automatic thirty-month stay of FDA approval of the ANDA, pending resolution of the patent claim.[67] Not surprisingly, as one observer has noted, "the most litigious corner of American industry today is almost certainly the initial marketing of generic drugs."[68] These suits are likely to increase in frequency as the patents of several billion-dollar pioneer drugs expire over the next few years.[69]

The Act also encourages generic manufacturers to file ANDAs quickly. The first ANDA filer may market its product as the only generic for 180 days.[70] This period begins once (1) a court declares the patent invalid or not infringed, or (2) the generic begins selling its version, whichever date is earliest.[71] During this time, the ANDA filer can establish much-needed name recognition and market share.[72]

At first glance, the Act appears to be a success for both private and public interests. Generic drugs have a larger share of the pharmaceutical market, and consumers have saved over $8 billion annually as

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63 35 USC § 271(e)(2) (2000). This section arguably created the

> highly artificial act of infringement that consists of [a generic's] submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent.

Eli Lilly v Medtronic, Inc, 496 US 661, 678 (1990).

64 21 USC § 355(b)(3), (j)(2)(B)(ii), (j)(5)(B)(iii).

65 See, for example, the buspirone patent litigation described in note 113.

66 A pioneer drug company's failure to sue an ANDA filer within forty-five days of receiving notice may result in the FDA's immediate approval of the ANDA. See *Eli Lilly*, 496 US at 677.

67 21 USC § 355(j)(5)(B)(iii).

68 Steven Andersen, *Generic Pharmaceuticals: IP's Fiercest Litigation Arena*, 13 Corp Legal Times 28 (Nov 2003) ("The litigation is complicated, time-consuming and expensive, but deemed necessary by both sides because of the money at stake."). See also Saritha Rai, *Generic Drugs from India Prompting Turf Battles*, NY Times C1 (Dec 26, 2003) (discussing international dimensions of pioneer-generic litigation).

69 Patented pioneer drugs generating over $20 billion in revenues that will come off patent in the next three years include $1.1 billion Cipro (2004), $3.2 billion Prevacid (2005), and $2.7 billion Zocor (2006). See Michael Johnsen, *Generic Drugs: Getting Poised for a Steeper Growth Curve*, 25 Drug Store News 35, 39 (Feb 17, 2003).

70 21 USC § 355(j)(5)(B)(iv).

71 Id.

72 See *Temporary Order Halts Ivax's Generic Metformin ER*, 20 Generic Line (Nov 5, 2003) (noting that a generic firm with 180 days of market exclusivity can capture "up to 80 percent of the brand's market within weeks of a launch").

a result.[73] However, the Act has also benefited pioneer drug companies by extending their average exclusive marketing period.[74]

Despite the Act's successes, its abuse has become widespread, especially among pioneer drug companies seeking to delay generic competition.[75] Until recently, a pioneer could file multiple patents and trigger additional stays on generic approval.[76] Pioneer and generic drug companies have also settled ANDA-related disputes through agreements that some courts have found to be anti-competitive.[77] While several commentators have advocated substantive changes to Hatch-Waxman,[78] this Comment examines whether the procedural inefficiencies caused by *Lexecon* undermine the Act's objectives.

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73 See Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 31 (July 1998), online at http://www.cbo.gov/showdoc.cfm?index=655&sequence=4 (visited Mar 7, 2004).

74 See id at 38 (finding that the average period of time between "when a brand-name drug enters the market and when its patent expires" increased from nine years in 1984 to eleven to twelve years for 1992–1995). In some cases, this exclusivity lasts longer than apparently envisioned by the Act. Even after winning a favorable district court judgment, a generic drug company may decline to market its version while an appeal is pending. See, for example, *TorPharm, Inc v Shalala*, 1997 US Dist LEXIS 21983, *4 (D DC) (noting that a preliminary injunction granted to compel the FDA to approve a generic's ANDA did not result in the generic drug's coming to market while an appeal was pending). A generic that markets its product and then loses on appeal may be ordered to compensate the pioneer for lost profits; such a damage award would likely be disastrous for the generic. See Elizabeth H. Dickinson, *FDA's Role in Making Exclusivity Determinations*, 54 Food & Drug L J 195, 198 (1999) ("[M]ost generic drug companies seem unwilling to risk liability for damages by bringing a generic drug product onto the market before the patent litigation is resolved.").

75 See generally Steve Seidenberg, *The Battle over Drug Patents: A U.S. Court Ruling Leaves Companies Facing Big Damages*, Natl L J A1 (July 15, 2002) ("It has become a common—and highly controversial—practice: The world's largest pharmaceutical companies, exploiting loopholes in federal drug laws, successfully stifle competition to their blockbuster drugs. Sometimes they keep competition off the market for years.").

76 The FDA now allows only one thirty-month stay for each ANDA, even when the pioneer has listed multiple patents. See FDA, *Applications for FDA Approval to Market a New Drug; Final Rule*, 68 Fed Reg 36676, 36677 (2003). Congress has enacted a similar provision. See *Congress Passes Medicare Reforms; Hatch-Waxman Amendments Included*, Espicom Business Intelligence (Dec 1, 2003).

77 Compare *In re Cardizem CD Antitrust Litigation*, 332 F3d 896, 908 (6th Cir 2003) (holding a pioneer's agreement to make payments to a generic in exchange for the latter's not marketing its product to be a "classic example of a per se illegal restraint of trade"), with *Valley Drug Co v Geneva Pharmaceuticals, Inc*, 344 F3d 1294, 1310 (11th Cir 2003) ("But if the payments were in furtherance of the seemingly reasonable purpose of compensating [the generic] for any lost profits during the course of litigation . . . , it is difficult to imagine how else to structure the payments but by tying them to the length of the litigation.").

78 See, for example, Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collective Settlements between Brand-Name and Generic Drug Manufacturers*, 17 Berkeley Tech L J 317, 334–35 (2002) (evaluating one proposed reform).

B. *Lexecon*-Related Trial Delays in Hatch-Waxman Multidistrict Litigation

As of this Comment's publication, the Panel has consolidated for pretrial proceedings ANDA-based claims related to four pioneer drugs: omeprazole[79] (sold under the brand name Prilosec), buspirone[80] (BuSpar), gabapentin[81] (Neurontin), and mirtazapine[82] (Remeron). In these MDLs, the pioneer drug manufacturer, as plaintiff, views the litigation itself as a critical means of delaying, if not completely preventing, generic competition.[83] This perspective manifests itself most clearly in the omeprazole litigation.

AstraZeneca markets omeprazole under the brand name Prilosec as a treatment for ulcers.[84] In the late 1990s, omeprazole was the most-prescribed drug in the world; its U.S. patent expired in 2001.[85] That year, omeprazole sales totaled approximately $5.7 billion, accounting for over one-third of AstraZeneca's revenues.[86] To protect these profits, AstraZeneca spent seven years developing dozens of business, regulatory, and legal strategies—including ANDA-based lawsuits—to delay generic competition.[87]

AstraZeneca began suing generics in May 1998.[88] In August 1999, the Panel consolidated AstraZeneca's cases against Andrx, KUDCo, and Cheminor in the Southern District of New York, where AstraZeneca was proceeding in an action against Genpharm.[89] Two years of pretrial proceedings provided Judge Barbara S. Jones a unique famili-

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79 See *Astra Aktiebolag v Andrx Pharmaceuticals, Inc*, 222 F Supp 2d 423, 432 (SD NY 2002).

80 See *In re Buspirone Patent Litigation*, 176 F Supp 2d 1374, 1374 (JPML 2001).

81 See *In re Gabapentin Patent Litigation*, 2001 US Dist LEXIS 1726, *2 (JPML).

82 See *In re Mirtazapine Patent Litigation*, 199 F Supp 2d 1380 (JPML 2002).

83 See Powell-Bullock, 29 J Legis at 29–34 (cited in note 53) (discussing the manipulation of the Hatch-Waxman system to delay the introduction of generic drugs).

84 See *Astra Aktiebolag*, 222 F Supp 2d at 432.

85 See *Prospects Fade This Year for Generic Prilosec*, 19 Generic Line (Apr 19, 2002).

86 See AstraZeneca, 2001 Annual Report, online at http://www2.astrazeneca.com/annualrep2001/inbrief/keyproductsummary.asp (visited Mar 3, 2004).

87 See Gardiner Harris, *Drug Prices: Why They Keep Soaring*, Wall St J A1 (June 6, 2002) (discussing these strategies). For example, AstraZeneca sought to switch its consumers over to Nexium, a slightly different drug with more recent patents. In addition to extending the Prilosec monopoly, ANDA-related litigation provided more time for this transition. However, managed-care group Kaiser Permanente discourages its physicians from prescribing Nexium because it "clearly is no value-added drug," according to one executive. See id.

88 See *Astra Aktiebolag v Genpharm*, No 98-CV-3657, docket at 3 (SD NY filed May 21, 1998).

89 See *Astra Aktiebolag v Andrx Pharmaceuticals*, No 99-CV-9887, docket at 4 (SD NY filed Sept 21, 1999). There was also a "second wave" of generic defendants that would be tried at a later date. See *Appeals Judge OKs KUDCo's Omeprazole, Blocks Others*, 20 Generic Line (Dec 24, 2003) (noting that these "second wave" cases have still not reached trial).

arity with the complex issues in the litigation, but *Lexecon*'s self-transfer prohibition prevented her from trying the cases immediately.

Instead, Judge Jones suggested to the Panel that it remand the cases. By August 31, 2001, Judge Jones had transferred these cases out of her court.[90] At Judge Jones's request, the transferor courts re-transferred the cases back to the Southern District of New York under § 1404(a) soon after the remands. On November 29, 2001, Judge Jones opened the last of the re-transferred cases, and a consolidated trial began.[91]

Although these remands and re-transfers adhered to the text of § 1407, they also prolonged significantly the exclusivity period of a blockbuster pioneer drug. In effect, the *Lexecon* decision provided AstraZeneca ninety-one additional days of omeprazole exclusivity,[92] and each day in litigation resulted in an average of $12 million in additional omeprazole sales.[93] Industry experts estimated generic competition to reduce omeprazole sales by 25–50 percent in the first year.[94] Thus, the additional period of omeprazole exclusivity caused by *Lexecon* earned AstraZeneca an estimated $270–540 million.[95] Although omeprazole consumers paid for most of these additional revenues, this burden extended to all taxpayers due to Medicaid prescription drug benefits.[96]

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90 See id. See also *Astra Aktiebolag v Andrx Pharmaceuticals*, docket at 5 (cited in note 89). See also *Astra Aktiebolag v Kremers Urban Development*, No 99-CV-9888, docket at 6 (SD NY filed Sept 21, 1999). The Genpharm actions remained in the transferee court because AstraZeneca had originally filed the case there. See *Astra Aktiebolag v Genpharm*, docket at 3 (cited in note 88).

91 See *Astra Aktiebolag v Andrx Pharmaceuticals*, docket at 6 (cited in note 89).

92 This delay is calculated as the number of days between the date the cases left the Southern District of New York (August 31, 2001) and the date the last case was re-transferred (November 29, 2001). See *Astra Aktiebolag v Andrx Pharmaceuticals*, docket at 5–6 (cited in note 89). This estimates the minimum delay conservatively because the defendants had been petitioning for the suggestion of remand order well before August 31, 2001.

93 See White, *Key Drug Patent Ruling Nears*, LA Times at C1 (cited in note 3).

94 See *AstraZeneca Soars on Ruling*, Toronto Star B2 (Oct 15, 2002) (estimating that generic competition could reduce Prilosec sales by 25–35 percent in the first year). But see Alex Grosvenor, *Health: Drug Companies—A Bitter Pill to Swallow*, FT Expatriate (Dec 1, 2002) (arguing that "while the erosion of sales won't be as rapid [for AstraZeneca] with just one copycat drug on the market, revenues could still slide by up to 50 per cent in a matter of weeks").

95 This figure is calculated by multiplying the daily revenue of Prilosec sales by ninety-one days and then multiplying by the range of a 25–50 percent sales decline. A precise figure would account for sales of Nexium and other pioneer drug substitutes, overall increases in drug spending, and several other factors. However, this estimate probably substantially captures the monetary value to AstraZeneca of *Lexecon* in delaying resolution of its patent infringement claims.

96 In 2001, private health plans accounted for 47 percent and Medicaid accounted for 17 percent of prescription drug expenditures in the United States. See Centers for Disease Control, National Center for Health Statistics, *Health, United States, 2003, Highlights from Trend Tables & Chartbook* 10 (CDC 2003), online at http://www.cdc.gov/nchs/products/pubs/pubd/hus/highlits.pdf (visited Mar 3, 2004). With the new Medicare drug benefit, the government's share of drug spending will likely increase. See Robert Pear, *Bush's Aides See Higher Price Tag for Drug*

The fifty-two-day bench trial in the omeprazole MDL illustrated the factual and legal complexity characteristic of drug patent litigation. AstraZeneca claimed the rights to five patents for various formulations and uses of omeprazole.[97] In October 2002, Judge Jones issued a 277-page opinion, holding that Genpharm, Cheminor, and Andrx had infringed AstraZeneca's patents, which the court deemed valid until 2007.[98] However, the court also held that KUDCo's product did not infringe any Prilosec patents.[99] Shortly after the ruling, Andrx and Genpharm transferred their rights to the 180 days of marketing exclusivity to KUDCo.[100] Despite AstraZeneca's appeal, KUDCo began marketing generic omeprazole in December 2002.[101] In December 2003, the Federal Circuit affirmed in an unpublished opinion.[102]

C. General Characteristics of Hatch-Waxman MDLs

Whatever objections generally arise in opposition to holding consolidated trials in transferee courts, the omeprazole litigation suggests that those arguments are misplaced in Hatch-Waxman MDLs. First, a consolidated trial avoids wasting the time of judges in several district courts needing to reacquaint themselves with highly technical factual disputes in a given drug patent litigation. In addition, trying the issue of patent validity in a single forum avoids the scenario of one court upholding the patent and another invalidating it. Moreover, there should be no choice-of-law concerns because these cases involve only federal patent law.[103]

Benefit, NY Times A1 (Jan 30, 2004) (discussing rising cost projections of the prescription drug benefit).

97 *Astra Aktiebolag*, 222 F Supp 2d at 432. Previously in the litigation, AstraZeneca asserted as many as eight patents. Id. The basic omeprazole patent expired on October 5, 2001. Id at 439.

98 Id at 505–47.

99 Id at 547–61.

100 In exchange, Andrx and Genpharm gained shares of KUDCo's omeprazole profits. See *Generic Industry Applauds Prilosec Approval, Launch*, 19 Generic Line (Nov 8, 2002) (noting that Andrx and Genpharm nevertheless intended to appeal the finding of infringement). See also Philippe Bennett, Thomas J. Parker, and Amy S. Manning, *Generic Battle Heats Up*, 11 Metro Corp Counsel 20 (June 2003) (explaining the FDA's unusual decision to have two generics share the 180-day exclusivity period).

101 See AstraZeneca, *AstraZeneca to Seek Treble Damages in Patent Infringement Lawsuit against Mylan Pharmaceuticals* (Aug 8, 2003), online at http://www.prnewswire.com/gh/cnoc/comp/985887.html (visited Mar 3, 2004) (noting that Mylan had announced that it had begun selling ten-milligram and twenty-milligram dosages of omeprazole). See also *Appeals Judge OKs KUDCo's Omeprazole, Blocks Others*, 20 Generic Line (cited in note 89) (discussing additional generics that have come to market, albeit without a favorable court decision).

102 See *Astra Aktiebolag v Andrx Pharmaceuticals*, 2003 US App LEXIS 24899, *5–8 (Fed Cir) (construing the patent claim of a "separating layer" in connection with a "subcoating" to not include any layer separating the core from the surrounding environment, and thus not anticipated by gelatin capsules).

103 See generally J. Clifford Wallace, *The Nature and Extent of Intercircuit Conflicts: A Solu-*

Most importantly, the common objection to trying cases in the transferee court—the respect due the plaintiff's choice of forum[104]—is inapposite to ANDA-based claims. In the Hatch-Waxman regime, whether a pioneer or generic initiates the litigation is less important than the fact that a federal court will resolve any questions of patent validity and infringement prior to FDA approval of a generic version. The Act effectively assigns the role of plaintiff to the pioneer by giving this party the first opportunity to sue after an ANDA has been filed.[105] It is not surprising that pioneers in Hatch-Waxman MDLs have consistently taken this opportunity. As the plaintiff, a pioneer drug company can use its procedural advantages to prolong litigation. Indeed, delaying generic competition in this manner is sometimes as valuable as winning the case.[106]

This unusual situation of a plaintiff delaying the resolution of its own claims as much as possible extends to multidistrict litigation. In a typical MDL, many plaintiffs sue one or a few defendants in different jurisdictions, and the latter seek § 1407 transfers to make their defense uniform and efficient.[107] In contrast, it is usually the pioneer drug company as plaintiff that seeks § 1407 consolidation of its own claims.[108] Yet, the pioneer usually could have avoided the need for such consolidation simply by filing all of its complaints against ANDA filers in one district. Indeed, § 1404 transfers like those following the remands in the omeprazole MDL are possible only if the transferee district is one where the cases might have been brought originally.[109] In multidistrict

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tion Needed for a Mountain or a Molehill?, 71 Cal L Rev 913 (1983) (discussing this need and arguing that the proposed cures for lack of uniformity are worse than the disease). Some circuits have required the transferee court to apply its interpretation of federal law, regardless of where the cases were originally filed. See, for example, *In re Korean Air Lines Disaster of September 1, 1983*, 829 F2d 1171, 1175 (DC Cir 1987) ("Applying divergent interpretations of the governing federal law to plaintiffs, depending solely upon where they initially filed suit, would surely reduce the efficiencies achievable through consolidated preparatory proceedings.").

104 See, for example, Benjamin W. Larson, Comment, Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach: *Respecting the Plaintiff's Choice of Forum*, 74 Notre Dame L Rev 1337, 1338 (1999) ("[T]he practice of self-transfer went unchecked for nearly three decades at the expense of plaintiffs whose rights were subjugated to prevailing concerns of efficiency and judicial economy.").

105 See note 64 and accompanying text.

106 See notes 64–69, 75–78, and accompanying text. This delay motive contrasts sharply with commonly perceived motives of plaintiffs and defendants. See, for example, John C. Coffee, Jr., *Class Wars: The Dilemma of the Mass Tort Class Action*, 95 Colum L Rev 1343, 1373 (1995) ("[T]he plaintiffs' attorney's tactical goal is to expedite cases, pushing them through the pipeline to the eve of trial (and predictable settlement).").

107 See Herrmann, 24 Litigation at 43–44 (cited in note 12) (discussing the circumstances of a typical MDL).

108 See, for example, *In re Omeprazole Patent Litigation*, 199 US Dist LEXIS 12589, *1 (JPML); *In re Buspirone*, 176 F Supp 2d at 1375; *In re Gabapentin*, 2001 US Dist LEXIS at *1; *In re Mirtazapine*, 199 F Supp 2d at 1380–81.

109 See *Hoffman v Blaski*, 363 US 335, 343–44 (1960) (holding that the phrase "might have

litigation, the pioneer drug company can turn the right of the plaintiff to choose her forum to its advantage to delay generic competition.[110] Whatever the traditional importance of the plaintiff's choice of forum,[111] courts should be wary of deferring reflexively to this interest in the context of Hatch-Waxman.

Finally, the remands and re-transfers in the omeprazole MDL are likely to recur in future MDLs because Hatch-Waxman claims seem unusually likely to reach trial. Patent disputes generally raise numerous factual questions,[112] any one of which would suffice to preclude summary judgment.[113] In addition, the pioneer drug company is usually reluctant to settle its ANDA-based claims unless doing so perpetuates its monopoly.[114] Even when this is possible, pioneers and generics will likely be wary of the growing scrutiny courts have applied to such agreements.[115]

D. Beyond Hatch-Waxman MDLs

For all multidistrict litigation, the *Lexecon* decision essentially enforces one rule: any cases transferred under § 1407 must be remanded after pretrial proceedings, absent a statutory instruction to the contrary. The inflexibility of this mandate has likely created inefficiencies in areas of federal law other than Hatch-Waxman. Like the omeprazole MDL, after the Panel remanded cases in one antitrust MDL to their original districts, almost every transferor court then transferred the cases under § 1404(a) to one district for trial.[116] This suggests that

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been brought" limits transfer to forums where the suit could have been filed at its outset). See also notes 7–10 and accompanying text.

110 See Herrmann, 24 Litigation at 43–44 (cited in note 12) (discussing the "time-consuming process" of initiating multidistrict litigation).

111 See, for example, *Gulf Oil Corp v Catrett*, 330 US 501, 508 (1947) ("[U]nless the balance is strongly in favor of the defendant, the plaintiff's choice of forum should rarely be disturbed.").

112 See *Tanabe Seiyaku Co v United States International Trade Commission*, 109 F3d 726, 731 (Fed Cir 1997) ("Whether a product or process infringes the properly construed claims of a patent . . . is a question of fact.").

113 See FRCP 56(c) (requiring "that there is no genuine issue as to any material fact" for summary judgment). But see *In re Buspirone Patent Litigation*, 185 F Supp 2d 340, 351–59 (SD NY 2002) (invalidating the patent on summary judgment). However, this MDL was unusual because Bristol-Myers Squibb (BMS) had only one relevant patent with a dubious history in the Patent and Trademark Office. See id at 346–50 (discussing the patent prosecution history). Even if the court had accepted BMS's construction, the patent would still have been invalid due to the obviousness of a prior art. Id at 359–62. Therefore, the only two possible constructions in the case led the court to the same conclusion: the single patent at issue was invalid.

114 See Steven Andersen, *Litigation Is the Business Model for Generic Drug Maker: Israel-Based Teva Takes On Name Brand Pharmaceutical Companies on U.S. Soil*, 13 Corp Legal Times 24 (Apr 2003) ("There's a huge incentive to bring the litigation against the generic company and a huge incentive not to settle with the generic company.").

115 See note 77.

116 The transferor courts transferred the cases to the Eastern District of New York, instead of simply re-transferring the cases to the transferee court in the Northern District of Illinois. See

Lexecon threatens judicial efficiency in certain situations.[117] In addition, the decision likely diminishes the transferee court's capacity to encourage settlement discussions.[118]

At the same time, the inflexible mandate of *Lexecon* saves other claims from the harms associated with self-transfer authority residing in the transferee court. The circumstances of *Lexecon* itself illustrate the extent to which litigating in a distant forum can disadvantage a party.[119] Moreover, such action could actually prove inefficient if one court applied the substantive law of many states in a consolidated trial.[120] Courts and litigants should tailor their responses to *Lexecon* to the circumstances. The next Part evaluates several ways to achieve that tailoring.

III. APPROACHES TO MINIMIZE *LEXECON*-RELATED INEFFICIENCIES

Every Congress since *Lexecon* has considered legislation to overrule the decision.[121] On March 22, 2004, the House approved the Mul-

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In re Brand-Name Prescription Drugs Antitrust Litigation, 264 F Supp 2d 1372, 1374 (JPML 2003) (noting that other cases were already pending in the Eastern District of New York). Without *Lexecon*, the transferee court presumably could have simply proceeded to trial or transferred the cases to a more appropriate jurisdiction. See also Stephen R. Stegich and David P. Yates, *MDL Consolidation of Aviation Disaster Cases before and after Lexecon*, 67 Def Counsel J 226, 231–34 (Apr 2000) (discussing an air crash MDL in which a similar series of remands and retransfers occurred).

117 See, for example, *In re Holocaust Era German Industry, Bank & Insurance Litigation*, 2000 US Dist LEXIS 11650 (JPML). After the Panel remanded the cases, the transferor court dismissed them because they presented nonjusticiable political questions. *Anderman v Federal Republic of Austria*, 256 F Supp 2d 1098 (CD Cal 2003). Any federal court, including the transferee court, could have resolved this constitutional issue, so there is no clear benefit to returning the cases to the transferor court.

118 Transferee courts have less influence over the parties to encourage settlement because they may not manage cases until their termination. See Multidistrict, Multiparty, Multiforum Trial Jurisdiction Act of 1999 and Federal Courts Improvement Act of 1999: Hearings on HR 2112 and HR 1752 before the Subcommittee on Courts and Intellectual Property of the House Committee on the Judiciary, 106th Cong, 1st Sess 55 (1999) (statement of John F. Nangle, Chairman, Judicial Panel on Multi-district Litigation and United States District Judge, Southern District of Georgia) ("The anticipation of trial in the transferee judge's court historically has provided powerful inducement to spawn global or individual settlements.").

119 See notes 40–43 and accompanying text.

120 See Hearings on HR 2112 and HR 1752, 106th Cong, 1st Sess 71 (cited in note 118) (statement of Brian Wolfman, Staff Attorney, Public Citizen Litigation Group) (arguing that vesting self-transfer power in the district court could disadvantage plaintiffs). However, this objection should not apply to purely federal claims—such as patent infringement—due to the goal of uniformity in federal law. See note 103.

121 The House in the 105th Congress passed HR 1252, but the bill never emerged from the Senate Judiciary Committee. See HR 1252, 105th Cong, 2d Sess, in 144 Cong Rec S 3585 (Apr 24, 1998). In the 106th Congress, both the House and Senate passed HR 2112, but the bill died in conference committee. See HR 2112, 106th Cong, 1st Sess, in 145 Cong Rec H 12020 (Nov 16, 1999). In the 107th Congress, the House passed HR 860, but the bill again languished in the Senate Judiciary Committee until Congress adjourned. See HR 860, 107th Cong, 1st Sess, in 147

tidistrict Litigation Restoration Act to amend § 1407 to authorize the self-transfer of any claim.[122] While enactment of such a bill would benefit Hatch-Waxman and other purely federal claims, an amended § 1407 in other contexts could resurrect the familiar criticisms of self-transfer involving choices of forum and law. Given the congressional reluctance to overrule *Lexecon* completely, judges and litigants should use existing procedural mechanisms to avoid *Lexecon*-related inefficiencies.

Unfortunately, these tools offer only two options to judges or litigants after the Panel has remanded Hatch-Waxman cases to the transferor courts. One is to hold trials in their courts, but this risks inconsistent determinations of patent validity. In addition, these courts will likely need to devote some time reacquainting themselves with the factual complexities lost during extensive consolidated pretrial proceedings.

Alternatively, the transferee court could request that transferor courts re-transfer the cases under § 1404(a) to the transferee court. As demonstrated by the omeprazole MDL, these remands and re-transfers simply delay for several months a trial that would be best conducted as one consolidated in the transferee court.[123] This limited range of imperfect options available late in litigation suggests that interested courts and parties should consider alternatives available earlier.

Although courts and litigants have at least four ways to minimize *Lexecon*-related delays in the MDL framework, there are practical obstacles complicating these strategies. A more efficient approach would extricate Hatch-Waxman claims from *Lexecon*-related delays altogether by relying on § 1404(a), not § 1407, transfers.

A. Possible Responses within the MDL Framework

1. Denial of § 1407 transfers by the Panel.

Generic drug manufacturers seeking to avoid *Lexecon*-related delays could simply oppose § 1407 transfer. The statute requires that transferred cases share "one or more common questions of fact" and that a transfer serve the "convenience of parties and witnesses" and promote "just and efficient" litigation.[124] The first requirement would

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Cong Rec H 898 (Mar 14, 2001).

122 The House passed the bill under the suspension of the rules. See HR 1768, 108th Cong, 2d Sess, in 150 Cong Rec H 1377 (Mar 24, 2004). This legislation states that transferor courts should determine compensatory damages, unless the transferee court finds that convenience and the interest of justice dictate otherwise. While this accords these damages technically different treatment, the substance of the bill provides general self-transfer authority.

123 See Part II.C.

124 See 28 USC § 1407(a) (listing when transfer is appropriate).

seem easily met in cases challenging the validity of the same drug patent, and the Panel has often overruled objections of inconvenience.[125]

Therefore, a generic would probably need to argue that multidistrict litigation is an inefficient approach for ANDA-related patent disputes. When the Panel anticipates little duplication of effort by multiple courts, it will sometimes deny transfer.[126] Another persuasive factor is the perception that voluntary coordination among several courts is an adequate alternative.[127] A pioneer usually sues a few generics, and these defendants could explain to the Panel how courts might coordinate their pretrial proceedings.[128]

The difficulty with this approach is that the Panel will still probably order transfer. In its thirty-five-year history, the Panel has ordered transfer 74 percent of the time.[129] Even though the factors described above are persuasive, the Panel has consolidated as few as two actions when doing so presumably reduced duplication of effort.[130] Indeed, the Panel rejected the argument that § 1407 transfers frustrate Hatch-Waxman's purpose and the promise of voluntary cooperation in creating the gabapentin MDL.[131] In addition, the Panel has often ignored

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125 See, for example, *In re Fine Paper Antitrust Litigation*, 685 F2d 810, 819–20 (3d Cir 1982):

> Although the district court [for the Eastern District of Pennsylvania] did not expressly quantify the interest in plaintiffs' convenience, it concluded that plaintiffs' convenience was outweighed by the comparative economy of trying one action in the Eastern District rather than several actions in the states' home districts. Given the complexity of the proceedings, we consider this conclusion to be reasonable.

126 This is particularly true when only a few related actions are pending. See, for example, *In re Fleet Bank Credit Card Terms Litigation*, 206 F Supp 2d 1368, 1369 (JPML 2002) (finding that centralization was not warranted when there were only two actions and counsel had cooperated, minimizing duplication).

127 See, for example, *In re Eli Lilly and Co (Cephalexin Monohydrate) Patent Litigation*, 446 F Supp 242, 244 (JPML 2002) (noting that "consultation and cooperation among the three concerned district courts ... coupled with cooperation of the parties, would be sufficient to minimize the possibility of conflicting pretrial rulings"). In addition, a generic could argue that transfer denial will likely lead to transferring related cases to one district under § 1404(a). Alternatively, the parties could agree to allow the pioneer to have its actions dismissed without prejudice and then refile its complaints in one district.

128 See, for example, id (discussing how to coordinate discovery in different courts).

129 As of December 31, 2003, the Panel had considered 1,580 requests for § 1407 transfer and consolidation. Among these, the Panel granted 1,009 and denied 351 requests. See statistics on file with author. The remaining requests were withdrawn, struck, rendered moot, or administratively closed. The estimate of 74 percent represents the proportion of granted motions divided by the sum of granted and denied motions.

130 See Charles Alan Wright, Arthur R. Miller, and Edward H. Cooper, 15 *Federal Practice and Procedure: Jurisdiction and Related Matters* § 3863 at 540–41 (West 2d 2003) (collecting cases).

131 See *In re Gabapentin Patent Litigation*, 2001 US Dist LEXIS 1726, *2 (JPML):

> Opponents to centralization base a significant part of their opposition on their concern that transfer will engender further delays in a litigation in which time is of the essence. Accordingly, they suggest that voluntary cooperation is a preferable alternative to Section 1407 transfer. We are sympathetic to this concern but view it as misplaced.

promises by the parties that they would coordinate pretrial proceedings voluntarily.[132] In sum, this approach might succeed, but it would be risky for a generic to rest its effort to avoid *Lexecon*-related delays on the Panel's denial of transfer.

2. Preemptive stipulations in the transferee court.

Another approach involves a transferee court urging the parties to stipulate around *Lexecon*. For example, the Eleventh Circuit affirmed judgment by one transferee court that had tried cases in which the parties stipulated that venue was proper there.[133] In another, the parties simply stipulated to trial in the transferee court.[134] By eliminating remands and re-transfers, this approach resembles self-transfer.[135] However, the scarcity of jurisdictions to condone this tactic suggests that it has not yet entered the judicial mainstream. At a minimum, the parties could stipulate to proper venue in the transferee court so that transferor courts could re-transfer cases more quickly after remand.[136] This would mitigate, if not eliminate, *Lexecon*-related delays.

Unfortunately, unlike the other approaches discussed in this Part, any stipulation necessitates agreement among the parties. The key obstacle in the Hatch-Waxman context is the probable refusal of the pioneer drug company to agree to expedite litigation. Perhaps a particularly persuasive transferee court could overcome this opposition,[137] but a pioneer seems likely to be more influenced by the additional profits gained by lengthy litigation.

3. Intercircuit transfer.

If the transferee court has nearly completed pretrial proceedings, the judge in that court could arrange her own intercircuit transfer to a

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132 See Wright, Miller, and Cooper, 15 *Federal Practice and Procedure* § 3863 at 540 n 49 (cited in note 130) (collecting cases).

133 See *In re Carbon Dioxide Industry Antitrust Litigation*, 229 F3d 1321, 1325–27 (11th Cir 2000) (upholding a trial after transfer to Florida of cases from California and Mississippi, over the objections of California and Mississippi parties after other parties settled).

134 See *In re Farmers Insurance Exchange Claims Representatives' Overtime Pay Litigation*, 300 F Supp 2d 1020, 1029 n 5 (D Or 2003) ("[I]f the parties stipulate to trial in the transferee district, the stipulation will be given effect.").

135 See *In re Brand-Name Prescription Drugs Antitrust Litigation*, 264 F Supp 2d at 1377 n 4:

> [A]lthough the *Lexecon* Court concluded that a transferee court could not transfer a case to itself for trial, the Court did not foreclose all possibility that a transferee judge could try an action that had been transferred to him or her under section 1407 so long as the parties waived ... remand.

136 Such a stipulation might include an agreement among the parties to submit only written briefs before the Panel and transferor courts, thus avoiding time-consuming oral arguments.

137 While a pioneer drug company would probably oppose these stipulations, it might not do so at the cost of antagonizing the court responsible for all pretrial proceedings—including summary judgment motions, motions to dismiss, and discovery orders.

transferor court to try one or more remanded cases.[138] For this to occur, the chief judge of the district or circuit to which the MDL judge would be transferred would certify the transfer's need to the Chief Justice of the United States.[139] The Chief Justice, in turn, would order the transfer.[140] After the cases are remanded, the MDL judge could try some of them in one transferor court. While respecting the plaintiff's choice of forum, intercircuit transfer is generally considered a cumbersome and inefficient procedure.[141]

The utility of this approach for Hatch-Waxman claims probably depends on the other transferor courts. If these courts immediately tried their cases after remand, this would expedite the resolution of all ANDA-related disputes.[142] Unfortunately, this approach could also produce inconsistent trial outcomes, such as one court upholding the pioneer's patent and another invalidating it. Moreover, these other trials would not harness the expertise of the MDL judge.

Alternatively, the other transferor courts could postpone trials until the MDL judge tries those claims before her. This would yield consistent trial outcomes,[143] and the other courts could benefit from the MDL judge's expertise by requesting her intercircuit transfer to their districts. However, multiple transfers would almost certainly delay the final resolution of all ANDA-related claims for a given pioneer drug even more than the re-transfers in the omeprazole MDL.[144]

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138 Hearings on HR 2112 and HR 1752, 106th Congress, 1st Sess 55–57 (cited in note 118) (statement of John F. Nangle, Chairman, Judicial Panel on Multi-district Litigation and United States District Judge, Southern District of Georgia) (discussing various transfer options). While the Panel remands any transferred cases, the MDL judge could transfer under § 1404(a) any cases originally filed in her district to a transferor court for a consolidated trial with any case(s) originally filed there.

139 See 28 USC § 292(d) (2000).

140 See id.

141 See, for example, Georgine Vairo, *Multidistrict Transfer*, Natl L J A19 (Mar 6, 2000) ("Although such a procedure comports with the *Lexecon* rule by protecting the litigants' original choice of forum, it can be a cumbersome and time-consuming process compared with transferring the cases directly to the transferee judge's regular docket for trial.").

142 In comparison to the delays in the omeprazole MDL, this approach would eliminate any re-transfers to the transferee court under § 1404(a), thus avoiding weeks of delay.

143 This assumes that the other transferor courts would not litigate again the issue of patent validity because that determination in the first trial would be barred by collateral estoppel. See *Blonder-Tongue Laboratories, Inc v University of Illinois Foundation*, 402 US 313, 349–50 (1971) (overruling a prior decision precluding a patent infringement defendant from arguing estoppel).

144 These transfers would obviously be unnecessary if the MDL judge invalidated the pioneer drug company's patent(s) in the first trial. See, for example, *In re Buspirone Patent Litigation*, 185 F Supp 2d 340, 363 (SD NY 2002) (holding that a later patent does not apply to the drug BuSpar). However, it seems more likely that Hatch-Waxman MDLs will generally involve several patents, at least one of which will be upheld. See, for example, *Astra Aktiebolag v Astra Pharmaceuticals*, 222 F Supp 2d 423, 505–47 (SD NY 2002) (applying plaintiff's patents to several defendants).

4. Adjudicate patent validity immediately in transferee court.

Yet another option exists when a pioneer drug company has filed one or more of its infringement claims in the transferee court.[145] That court could try the question of patent validity in such a case while the Panel remands the other cases.[146] Once resolved, the validity determination would bind all generics as res judicata,[147] so the transferee court should request amicus curiae briefs on the validity issue from all generics. If the transferee court upholds the patent(s), then all courts could try the infringement claims.

Although this strategy produces a consistent determination of validity, it may prove cumbersome in practice. Indeed, if one of the pioneer's patents is declared valid, the pioneer drug manufacturer will have the burden of litigating its infringement claims in multiple courts simultaneously.[148] Finally, this approach draws on the MDL judge's factual expertise for only one-half of the litigation, leaving the unfamiliar transferor courts to determine infringement.

B. Best Response: Early § 1404 Transfers

The clear need for consolidated discovery and trial in related ANDA-based claims suggests that courts handling such cases should use non-MDL procedures to transfer and consolidate them. One of these courts—probably the first district in which the pioneer filed a complaint—will likely be furthest along in pretrial proceedings.[149] To avoid any delays caused by multidistrict litigation in general, defendant generics should request that courts transfer the patent cases to this leading jurisdiction under § 1404(a). The transferee court could then consolidate these claims for trial under Rule 42(a). This approach achieves the efficiencies of consolidated discovery and trial demon-

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145 This will usually be the case because the Panel strongly prefers to designate a district currently handling at least one of the related cases as the transferee court. See, for example, note 149 and accompanying text (explaining the Panel decision to choose the transferee court in the omeprazole MDL). See also Wright, Miller, and Cooper, 15 *Federal Practice and Procedure* § 3864 n 9 at 454–55 (cited in note 130) (collecting cases).

146 The judge in the transferee court could try the generic's cross-claim alleging patent invalidity before the pioneer's claim alleging infringement under FRCP 42(b).

147 See *Blonder-Tongue*, 402 US at 349–50 (discussing the application of estoppel to patent cases).

148 However, one might have little sympathy for such a concern because litigating in several forums apparently respects this plaintiff's choice.

149 If the Panel were to transfer and consolidate these cases, it would likely choose such a district to serve as the transferee court. See Wright, Miller, and Cooper, 15 *Federal Practice and Procedure* § 3864 n 16 at 461 (cited in note 130) (collecting cases). See, for example, *In re Omeprazole*, 1999 US Dist LEXIS 12589, *3 (JPML) ("[T]he Southern District of New York is the most appropriate transferee forum for this litigation [because, in part,] two actions are proceeding apace in the New York court before Judge Barbara Jones.").

strated by the omeprazole MDL while avoiding the months of remands and re-transfers required by *Lexecon*.

To persuade a district court to transfer, a generic should argue that doing so would promote party and witness convenience and serve the interest of justice.[150] Clearly, consolidating all discovery and trial proceedings in one district would be the most convenient approach for the pioneer drug company and any witnesses.[151] More importantly, § 1404(a) transfer serves the broadly phrased "interest of justice"[152] because the likely alternative, multidistrict litigation, frustrates the purpose of the Hatch-Waxman Act. Congress deemed lowering pharmaceutical prices through competition so important that it designed a distinct legal and regulatory framework specifically for prescription drug patent disputes. *Lexecon*-related delays frustrate this purpose, and a district court may better weigh such considerations than a Panel responsible for transferring thousands of cases annually.[153]

Although the restriction that the transferee court be one in which the case "might have been brought"[154] could pose problems for certain kinds of multidistrict litigation, it should not be a significant obstacle here. For corporate defendants sued under patent laws, venue is proper in any district in which the defendant is subject to personal jurisdiction.[155] Personal jurisdiction turns largely on purposeful contacts with the forum state.[156] Generic drug manufacturers have probably engaged in such contacts with most jurisdictions and thus have met venue and personal jurisdiction requirements.[157] If § 1404(a) transfers like those in the omeprazole MDL can meet personal jurisdiction and

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150 See 28 USC § 1404(a). If the generic does not move for transfer, a court may order it on its own. See, for example, *Kelly v Kelly*, 911 F Supp 70, 71 (ND NY 1996) ("Though courts rarely transfer cases on their own initiative, the statute clearly permits this when the interests of justice would be best served by doing so.").

151 If the pioneer sues the generic in the latter's home district, § 1404(a) transfer anywhere else would presumably make litigation less convenient for the generic. However, the generic can adequately represent its interest in convenience, and it should still move for transfer to avoid *Lexecon*-related delays.

152 See Wright, Miller, and Cooper, 15 *Federal Practice and Procedure* § 3854 at 441 (cited in note 130) (discussing the wide variety of factors considered under this imperative).

153 See note 131 (quoting the Panel's consideration of arguments about Hatch-Waxman's purpose in the gabapentin MDL).

154 28 USC § 1404(a). For a more detailed explanation of this limitation, see notes 7–10 and accompanying text.

155 28 USC §§ 1391(c), 1400(b) (2000).

156 See, for example, *LG Electronics Inc v First International Computer, Inc*, 138 F Supp 2d 574, 588 (D NJ 2001) (applying this analysis in a patent dispute).

157 See Kimberly A. Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?*, 79 NC L Rev 889, 894–901 (2001) (discussing how the breadth of modern venue statutes enables plaintiffs in patent litigation to forum shop).

venue requirements after remand, then they must have been able to have satisfied them earlier as well.[158]

It is possible that only some courts handling related Hatch-Waxman claims will transfer them under § 1404(a). The leading jurisdiction should encourage all courts to order transfer, but, if a few courts refuse, the defendant generics might still be in a stronger position to oppose § 1407 transfer before the Panel. The Panel sometimes considers procedural alternatives in deciding whether to order § 1407 transfer.[159] In Hatch-Waxman claims, the Panel might be more likely to deny § 1407 transfer if § 1404(a) transfers in related cases have demonstrated their viability.[160]

CONCLUSION

By delaying the arrival of a generic competitor involved in a Hatch-Waxman MDL, *Lexecon* frustrates the purpose of the Hatch-Waxman Act—to promote prescription drug competition. Congress has been reluctant to amend § 1407, so courts assigned related Hatch-Waxman claims should transfer them under § 1404 to a leading jurisdiction.

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158 See *Hoffman v Blaski*, 363 US 335, 342–43 (1960) (holding that the relevant determination for where a case may have been brought involves the circumstances at the commencement of the litigation).

159 See note 127 (discussing the denial of transfer when informal, voluntary coordination is a viable alternative).

160 See Wright, Miller, and Cooper, 15 *Federal Practice and Procedure* § 3863 n 40 at 541 (cited in note 130) (collecting cases on suitable alternatives to § 1407 transfers).